

**3. RESPONSE/REMARKS:**

**3.1 STATUS OF THE CLAIMS:**

*Claims 1-31, 35, and 39-40 were pending at the time of the Action.*

*Claim 6 was canceled herein without prejudice and without disclaimer.*

*Claims 1, 7, 14, 17, 22, 24, 26-28 and 30 have been amended herein.*

*Claims 1-5, 7-31, 35 and 39-40 remain pending in the case.*

**3.2 SUPPORT FOR THE CLAIMS:**

Support for the pending claims can be found throughout the original specification, claims, and figures as filed. Applicants certify that no new matter is included by entry of this paper.

Although no fees are believed to be due in connection with entry of the present amendment, should any fees be deemed necessary for any reason, the Commissioner is hereby authorized to deduct any necessary amounts from Deposit Account No. 08-1934, Order No. 36677.8.

**3.3 A NEW INVENTOR'S DECLARATION IS PROVIDED.**

*The Action at page 2 objected to original declaration filed on December 28, 2005, allegedly because it listed the foreign priority document, Australian application AU PP6165, under 35 U. S. C. § 120, when it should have been listed under §119(a)-(d).*

Applicants have corrected this oversight by providing a new declaration enclosed herewith, and ask that the rejection now be withdrawn.

### 3.4 THE OBJECTION TO CLAIM 7 IS OVERCOME.

*The Action at page 3 objected to claim 7 for omission of the word "in" before "General Formula II."*

Applicants have corrected this inadvertent typographical error, and now ask that the rejection be withdrawn.

### 3.5 THE REJECTION OF CLAIMS UNDER 35 U. S. C. § 112, 2<sup>ND</sup> PAR., IS OVERCOME.

*The Action at page 4 rejected claims 1-31, 35, and 39-40 under 35 U. S. C. § 112, 2<sup>nd</sup> paragraph, allegedly as being indefinite. Specifically,*

*at Item 11, claims 1-16 and 35 were rejected because the Examiner considers that the claim does "not indicate which molecule is the primary amine nitrogen atom belongs to, and how the linear or cyclic peptide, the C-terminal modified peptide, or on-resin cyclization of a peptide molecule is synthesized via the auxiliary compound."*

Applicants respectfully traverse, and again point out to the Office that it is not necessary to specify any additional method steps in either of the independent claims (claims 1 and 14), since the skilled artisan would understand on a fair reading of the Specification as a whole, and particularly by reference to Scheme 13 at page 58 that it is the *presence* of the electron-withdrawing group in the auxiliary which facilitates conversion of the amine to an amide.

However, with a view to progressing the application to allowance, and without prejudice, Applicants have chosen to further clarify the language of claims 1 and 14 to recite an activation step. This activation step is inherently present in step (b) of claims 24, 26 and 30, and it is a standard step in solid-phase peptide synthesis. Thus, in claims 24, 26 and 30 it would be evident to the skilled addressee of the Specification that the step of activation of the carboxylic acid group of each amino acid which is to be sequentially added is inherent in the reference in

sub-paragraph (b) to “standard solid-phase synthesis methods.” To that end, Applicants assert that it is both unnecessary and superfluous to add a separate step reciting that which is well-understood by the skilled artisan.

*At Item 12, claim 6 was rejected because the Examiner considers the claim of the same scope as claim 1.*

Applicants have canceled claim 6, since the specified auxiliary has now been incorporated into claim 1. Thus, the present rejection is now moot, and Applicants respectfully ask that it be withdrawn.

*At Item 13, claims 17-21, 23, and 39 were rejected because the Examiner considers it is unclear how the auxiliary compound assists the synthesis of a cyclic peptide.*

Applicants respectfully traverse; however, as noted above, Applicants have amended claims 1 and 14 to more distinctly point out the location of the primary amine nitrogen atom, and to refer to the step of activating the C-terminal carboxylic acid group. Applicants believe that this response fully addresses the Examiner’s concern, as the recited steps would be clearly understood by one of skill in the art having benefit of the teachings of the Specification. Applicants respectfully request, therefore, that the rejection be withdrawn.

*At Item 14, claims 20 and 39 were rejected because the Examiner considers the language to be indefinite as to “where in the linear peptide the solid support is connected to.”*

Applicants respectfully traverse, and note that it would be evident to a person skilled in the art that the solid support in claim 20 may be linked to any site in the peptide (*i.e.*, the termini,

backbone, or even a side-chain). This is clearly described in the Specification (see e.g., the flow charts on page 24, in which a peptide nitrogen atom is linked *via* the auxiliary to the solid support). Similarly, this is illustrated on page 65. Likewise, Scheme 10 on page 38, and Scheme 11, on page 45, show linkage of the peptide to the support *via* the C-terminal carboxylic acid group. It is submitted that there is no need to specify this in the claims, as it would be apparent to one of skill in this art what the Applicants embrace by the existing claim language, and as such Applicants respectfully request that the rejection be withdrawn.

*At Item 15, claims 22 and 40 were rejected allegedly as indefinite “as to how the auxiliary compound assists the synthesis of a large peptide since the claim only recites the steps of linking an auxiliary compound to the primary amine of the first peptide fragment, activating the C-terminal carboxylic acid of the second peptide fragment, adding the second peptide fragment to the first peptide fragment to form a peptide bond....” The Examiner considers the language to be indefinite because it “does not indicate how the peptide is formed via the auxiliary compound.”*

Again, Applicants respectfully traverse, and submit that it would be evident to a person skilled in this art that step (d) recited in the claim may be performed as many times as necessary to build up the large peptide. As such, Applicants again respectfully request that the rejection be withdrawn, as there is no additional language necessary to make the claim “clear” and “definite” to one of skill in these arts.

*At Item 16, claims 24 and 25 were rejected allegedly as indefinite because of the use of the term “a) linking an auxiliary compound as defined in claim 1 to one or more nitrogen atoms in peptide bonds of a peptide linked to a solid support” as to how the auxiliary compound assists the synthesis of a large peptide since the claim only recites the steps of linking an auxiliary compound to the primary*

*amine of the first peptide fragment, activating the C-terminal carboxylic acid of the second peptide fragment, adding the second peptide fragment to the first peptide fragment to form a peptide bond....”*

*The Examiner considers the language to be indefinite because it “does not indicate how the peptide is formed via the auxiliary compound.”*

Again, as noted in response to item 15, Applicants respectfully traverse and submit that it would be perfectly clear to a skilled artisan in this field having benefit of the teachings of the Specification, that the peptide in step (a) is a starting sequence from which the final difficult peptide is to be built up. Applicants respectfully request, therefore, that this rejection also be withdrawn.

*At Item 17, claims 26-29 were rejected allegedly as indefinite “as to how the auxiliary compound is involved in the backbone linkage for synthesis of a linear peptide since the claim recites linking an auxiliary compound to an alpha-nitrogen of an amino acid in the peptide to a solid support, and assembling the linear peptide using standard solid phase synthesis.”*

Applicants again respectfully traverse and submit that the plain language of claim 26 would be perfectly clear to a skilled artisan in this field having benefit of the teachings of the Specification, and in particular, by reference to the diagrams at pages 22 and 24. Applicants therefore ask that the rejection now be withdrawn.

*At Item 18, claims 27 and 28 were rejected allegedly as indefinite “as to the carboxylic acid group of the C-terminal amino acid residue is replaced by a functional group, it is not clear which step (e.g., step a), b), c), or d)) the carboxylic acid is replaced.” Also, at Item 19, claim 28 was further rejected due to unclear antecedent basis.*

Applicants have addressed the concerns of the Examiner by clarifying the language as

shown in the accompanying amendment. Basis for this amendment is found at page 20 lines 12 to 19 of the specification. The dependency of claim 28 is now taken from claim 27, and not claim 26, and the clarifying language is provided. It would be evident to the skilled addressee of the present Specification that the modification is made in the course of synthesis of the selected peptide; clearly this can be effected either by modification of the selected peptide itself, or by using a modified amino acid in the course of its synthesis. Applicants respectfully request that in view of this clarification, the present rejection be withdrawn.

*At Item 20, claims 30 and 31 were rejected allegedly as indefinite “as to how the auxiliary compound is involved in on-resin cyclization of a linear peptide since the claim recites linking an auxiliary compound to an alpha-nitrogen of an amino acid residue in the desired peptide to a solid support, and synthesizing the linear peptide using standard solid phase synthesis.”*

Applicants respectfully traverse, however, in an interest of facilitating ready allowance of all pending claims, claim 30 has been amended to more particularly point out what Applicants view as their invention, and to provide greater clarity with respect to how the auxiliary is involved. Therefore, in view of the present amendment, Applicants respectfully request that the rejection be withdrawn.

### **3.6 CONCLUSION**

It is respectfully submitted that all claims are fully enabled by the Specification, and that all claims are definite, and free of the prior art. Applicants believe that the claims are acceptable under all sections of the Statutes and are now in conditions for ready allowance, and that all of the

concerns of the Examiner have been resolved. Applicants earnestly solicit concurrence by the Examiner and the issuance of a Notice of Allowance in the case with all due speed.

Applicants note for the record their explicit right to re-file claims to one or more aspects of the invention as originally claimed in one or more continuing application(s) retaining the priority claim from the present and parent cases.

Should the Examiner have any questions, a telephone call to the undersigned Applicants' representative would be appreciated, and in particular in advance of any subsequent action on the merits.

Respectfully submitted,



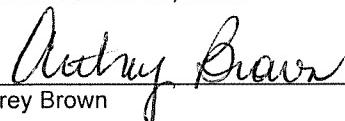
Mark D. Moore, Ph.D.  
Registration No. 42,903

Date: October 25, 2006  
  
HAYNES AND BOONE, L.L.P.  
901 Main Street, Suite 3100  
Dallas, Texas 75202-3789  
Telephone: 713-547-2040

Facsimile: 214-200-0853  
36677.8

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I hereby certify that this correspondence is being filed with the U.S. Patent and Trademark Office via EFS-Web on October 25, 2006.

  
Autrey Brown